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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,188	03/24/2004	Richard Deslauriers	22469-005001	4577

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EXAMINER	
WELTER, RACHAEL E	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
09/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/808,188	DESLAURIERS ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/15/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *413-416 and 420-422* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *413-416 and 420-422* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/15/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 413-416 and 420-422 are pending. Claims 1-412 and 417-419 are cancelled. Claims 420-422 are newly added.

Acknowledgements

Receipt of the amendment and arguments/remarks filed on 7/15/10 is acknowledged.

Information Disclosure Statement

The information disclosure statement (IDS) submitted July 15, 2010 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered by the examiner. A signed copy of form 1449 is enclosed herewith.

Withdrawn Rejections

The rejection of claims 397-408 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendments.

The rejection of claims 413-416 rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (Rev. Bras. Ortop., Vol. 32, No. 10, 1997) in view of Arnett (US Patent No. 6,506,217) is withdrawn in light of applicant's amendments.

The rejection of claims 417-418 rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (Rev. Bras. Ortop., Vol. 32, No. 10, 1997) in view of Arnett (US Patent No. 6,506,217) as applied to claims 413-416 above and in further view of Nathan et al (US Patent No. 7,030,127) is withdrawn in light of applicant's amendments.

The rejection of claim 419 rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (Rev. Bras. Ortop., Vol. 32, No. 10, 1997) in view of Arnett (US Patent No. 6,506,217) as applied to claims 413-416 above and in further view of Nakabayashi et al (US Patent No. 5,264,215) is withdrawn in light of applicant's amendments.

The rejection of claims 409-410 rejected under 35 U.S.C. 103(a) as being unpatentable over Adhikari et al (WO 2004/009227) in view of Arnett (US Patent No. 6,506,217) is withdrawn in light of applicant's amendments.

The rejection of claims 397-408 and 412 rejected under 35 U.S.C. 103(a) as being unpatentable over Adhikari et al (WO 2004/009227) in view of Arnett (US Patent No. 6,506,217) and Sandvig et al (US Patent No. 5,800,899) is withdrawn in light of applicant's amendments.

The rejection of claim 411 rejected under 35 U.S.C. 103(a) as being unpatentable over Adhikari et al (WO 2004/009227) in view of Arnett (US Patent No.

6,506,217) as applied to claims 409-410 above and in further view of Nathan et al (US Patent No. 7,030,127) is withdrawn in light of applicant's amendments.

New Rejections

The following rejections constitute new grounds for rejection necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 413 and 420-422 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felt et al (US Patent No. 6,140,452; Published 10/31/2000) in view of Arnett (US Patent No. 6,506,217; Published 1/14/2003).

Felt et al teach the administration of a flowable composition comprising a curable polyurethane biomaterial. The composition can be delivered using minimally invasive means to a tissue site and there fully cured providing a permanent and biocompatible prosthesis for repair of the tissue site (abstract; column 7, lines 19-35). The invention is particularly useful for bone and cartilage repair and replacement (column 1, lines 18-21). The composition is delivered through microsurgical or endoscopic or arthroscopic surgical means (column 11, lines 26-38). The biomaterials are modified in situ, at the tissue site, in order to undergo a phase or chemical change sufficient to retain a desired position and configuration (column 12, lines 31-34). Felt et al teach that inorganic fillers, such as calcium carbonate, titanium dioxide, or barium sulfate can be added to the composition to affect viscosity and thixotropic properties of the resultant mixture (column 20, lines 47-52).

Felt et al do not explicitly teach the step of manipulating said bone scaffold composition in situ using external pressure applied to the skin of the patient after administration of the composition but before the composition is fully cured.

Arnett teaches the implantation of a bone filler and bone conforming material via surgery, wherein after surgery, the surgeon can continue to adjust or modify the contours of the patient body in the areas with the bone conforming material by applying pressure to the skin, muscle, and other tissue overlaying the implant to thereby mold or shape the implanted bone conforming material (column 2, lines 24-34).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to apply external pressure to the skin of patients in order to manipulate the polyurethane composition of Felt et al. One would have been motivated to do so since Arnett suggests that it is conventional after implanting bone filler to mold or shape the implanted material externally by applying pressure to the skin overlapping the bone conforming material. It also would have been obvious to further shape the bone conforming material in such a way because it is non-invasive and enables the surgeon to improve aesthetic results. Even though Arnett teaches molding and shaping of an already polymerized implant, it would have been obvious to manipulate the composition of Felt et al before it is fully cured. One would have been motivated to do so since the composition has not hardened an it would be easier to manipulate to a desired position and configuration.

Regarding the limitations wherein the composition is osteoconductive and osteoinductive, it is the examiner's position that such properties would be implicit since Felt et al teach all the components of the instant composition. According to MPEP 2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the

prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)*. Burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).*

Claims 414-416 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felt et al (US Patent No. 6,140,452; Published 10/31/2000) in view of Arnett (US Patent No. 6,506,217; Published 1/14/2003) as applied to claims 413 and 420-422 above and in further view of Chierice (PI 006544-7; Published 5/6/2001; See English Translation in IDS mailed 3/24/2004).

The disclosures of Felt et al and Arnett are discussed above.

Felt et al and Arnett do not teach a composition comprising a castor-oil based polyurethane.

Chierice teaches biocompatible polyurethane derived from castor oil that can be used in the manufacturing of prostheses, membranes, bony filler, and cement in prostheses fixing (see pg. 1 of English translation). According to Chierice, the polyurethane has the capacity to be synthesized with different mechanical properties in varied formats.

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to incorporate castor-oil based polyurethane in the composition of Felt et al. One would have been motivated to so since Chierice teaches that such polyurethanes are desirable in the manufacturing of prostheses and the compositions of

Felt are particularly useful for bone/cartilage repair and replacement. Furthermore, one would have been motivated to use castor-oil based polyurethane because Chierice suggests that they have the capacity to be synthesized with different mechanical properties. Thus, if an artisan desired a composition with particular mechanical properties, it would have been obvious to select castor-oil based polyurethane because of its adaptability and likelihood that it would achieve a particular mechanical property.

Response to Arguments

Applicant's arguments with respect to the Non-Final rejection mailed 1/15/10 have been considered but are moot in view of the new ground(s) of rejection above.

It is noted that the rejection is based on a new primary reference, Felt et al. It is noted that Felt et al teach a flowable polyurethane composition and Arnett is combined with Felt only to teach the manipulation of a composition in situ using external pressure applied to the skin of a patient. Further, Felt teaches that their compositions are administered through the skin via microsurgical or endoscopic or arthroscopic surgical means.

Although applicant argues that Arnett teaches away from manipulating a flowable composition using external pressure applied to the skin of a patient, the examiner respectfully disagrees. Applicant is directed to MPEP 2123. Arnett does not explicitly criticize, discredit, or necessarily discourage manipulating a flowable composition, such as the composition of Felt before it is hardened/cured. It is noted that the implant material of Arnett is different than both the instant invention and Felt. As such,

elimitation of the hardening step in Arnett may not be as optimal as the instant invention and/or Felt. Applicant is reminded that the rejection above is based on the combination of Felt and Arnett and manipulating the composition of Felt using Arnett's method of applying external pressure on the skin. Arnett may teach molding and shaping of an already polymerized implant, however, it is the examiner's position that it would have been obvious to manipulate the composition of Felt et al externally before it is fully cured. One would have been motivated to manipulate Felt's composition externally since the composition is more flowable before curing and thus it would be easier to manipulate to a desired position and configuration. According to Ex parte RUBIN, 128 USPQ 440 (Bd. Pat. App. & Int. 1959), it has been held that merely reversing the order of steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. Thus, unless applicant provides evidence of any unexpected advantage over the method of the prior art, the method carries no patentable weight.

Conclusion

Claims 413-416 and 420-422 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643